

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

GOVERNMENT'S MOTION TO SCHEDULE A RULE 11 HEARING

The United States of America, through the undersigned attorneys, does hereby move to schedule a hearing pursuant to Rule 11 of the Federal Rules of Criminal Procedure. In support of this motion, the government states that the defendant has agreed to plead guilty to the Information attached hereto. The parties request a hearing on January 9, 2019 if convenient for the Court.

Respectfully submitted,

ANDREW E. LELLING
United States Attorney

By: s/ Fred M. Wyshak, Jr.
Fred M. Wyshak, Jr.
K. Nathaniel Yeager
David Lazarus
Assistant U.S. Attorneys

Date: December 26, 2018

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA)	Criminal No.
)	Violations:
v.)	
MICHAEL L. BABICH,)	<u>Count One: Conspiracy</u>
)	(18 U.S.C. § 371)
Defendant)	<u>Count Two: Mail Fraud; Aiding and Abetting</u>
)	(18 U.S.C. §§ 1341 and 2)
)	<u>Forfeiture Allegation:</u>
)	(18 U.S.C. § 981(a)(1)(C) and
)	28 U.S.C. § 2461)

INFORMATION

At all times relevant to this Information:

General Allegations

1. Insys Therapeutics, Incorporated, was a Delaware corporation with headquarters in Chandler, Arizona (“Insys” or “the Company”). Insys developed and owned a drug called “Subsys,” a liquid formulation of fentanyl to be applied under the tongue. From in or about March 2012, until in or about September 2018, Insys marketed and sold Subsys in interstate commerce, including in the District of Massachusetts

Subsys

2. The United States Food and Drug Administration (“FDA”) approved Subsys in or about January 2012 for the management of breakthrough pain in patients 18 years of age or older with cancer who were already receiving, and who were already tolerant to, opioid therapy for their underlying persistent cancer pain.

3. Subsys was a fentanyl-based, rapid onset opioid. Subsys was designated as a Schedule II controlled substance by the United States Drug Enforcement Administration (“DEA”). As such, Subsys was required by law to be under the control of a DEA-registered entity until it reached the patient or it was destroyed.

4. Federal law mandates that to be effective, a prescription for Subsys must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. Subsys could only be prescribed by a licensed medical practitioner, who was registered with the DEA and able to prescribe opioids in the usual course of professional practice, for a legitimate medical purpose. Practitioners owed a fiduciary duty to their patients to prescribe Subsys in the usual course of professional practice for a legitimate medical purpose.

Insurance

5. Most patients relied upon commercial insurance and/or publicly-funded insurance, including Medicare and Medicaid, to subsidize the cost of Subsys. While their specific requirements varied, almost all insurers required patients to obtain prior authorization before agreeing to pay for a Subsys prescription. In such cases, insurers would not authorize payment if the prescription was written: (a) in exchange for a bribe or kickback; (b) outside the usual course of professional practice; or (c) not for a legitimate medical purpose. In general, patients had to receive a particular medical diagnosis before the insurer would authorize payment for Subsys. In addition, many insurers would not pay for Subsys until the patient had tried and failed certain other preferred medications.

6. If the insurer authorized payment for Subsys, the insurer paid most, but not all, of the cost of the drug. Without prior authorization, the prescription was not filled unless the

patient or a third party paid for the entire cost of Subsys.

Co-Conspirators

7. JOHN N. KAPOOR (“KAPOOR”) founded and owned Insys. KAPOOR held executive management positions at Insys, including Executive Chairman of the Board of Directors, and for a time, Chief Executive Officer (“CEO”).

8. Defendant **MICHAEL L. BABICH** (“BABICH”) held executive management positions at Insys, including President and CEO.

9. ALEC BURLAKOFF (“BURLAKOFF”) held executive management positions at Insys, including Regional Sales Manager for the Southeast Region and Vice President of Sales.

10. MICHAEL J. GURRY (“GURRY”) held executive management positions at Insys, including Vice President of Managed Markets.

11. RICHARD M. SIMON (“SIMON”) held executive management positions at Insys, including Regional Sales Manager for the Central Region and National Director of Sales.

12. SUNRISE LEE (“LEE”) held executive management positions at Insys, including Regional Sales Manager for the Mid-Atlantic Region, Regional Director for the Central Region, and Regional Director for the West Region.

13. JOSEPH A. ROWAN (“ROWAN”) held executive management positions at Insys, including Regional Sales Manager for the Southeast Region and Regional Director for the East Region.

COUNT ONE
Conspiracy
(18 U.S.C. § 371)

14. The United States Attorney re-alleges and incorporates by reference paragraphs 1 through 13 of this Information as if fully set forth herein, and charges that:

15. In or about and between at least May 2012 and December 2015, both dates being approximate and inclusive, the defendant,

MICHAEL L. BABICH,

conspired with others, known and unknown to the United States Attorney, including Kapoor, Burlakoff, Gurry, Rowan, Simon, and Lee, to commit violations of:

- a. Title 18, United States Code, Section 1341 (mail fraud);
- b. Title 18, United States Code, Section 1343 (wire fraud);

Object of the Conspiracy and Scheme to Defraud

16. The Defendant and his co-conspirator sought to increase profits for Insys and themselves through bribes and fraud, in connection with the sale of Subsys, a product containing a Schedule II opioid.

Manner and Means of the Conspiracy and Scheme to Defraud

17. It was part of the conspiracy that the Defendant and his co-conspirators intentionally bribed and provided kickbacks to practitioners in order to increase Subsys sales. The Defendants provided bribes and kickbacks to targeted practitioners, in exchange for the practitioners:

- a. increasing the number of new Subsys prescriptions; and

b. increasing the dosage and number of units of Subsys for new and existing prescriptions.

18. The Defendant and his co-conspirators arranged and coordinated the bribes and kickbacks using interstate wire transmissions, including emails, texts, and telephone calls.

19. The bribes and kickbacks took multiple forms:

- a. The defendant and his co-conspirators paid bribes and kickbacks that were disguised as honoraria purportedly for practitioners' participation in educational events called "Insys Speaker Programs" or "ISPs."
- b. The defendant and his co-conspirators hired and paid the salaries of members of the office staff for certain targeted practitioners to perform administrative tasks that the practitioners would have otherwise had to pay someone else to perform.

Overt Acts In Furtherance of the Conspiracy

20. In furtherance of the conspiracy and to achieve the objects thereof, the defendant **MICHAEL L. BABICH** and his co-conspirators committed and caused to be committed, in the District of Massachusetts and elsewhere, the following overt acts, among others:

- a. On or about August 20, 2013, check number 11696, payable to Practitioner 1, for \$2,400 was mailed to Practitioner 1.
- b. On or about May 21, 2014, check number 3102, payable to Practitioner 2, for \$1,600 was mailed to Practitioner 2.
- c. On or about April 22, 2013, check number 10772, payable to Practitioner 3, for \$1,600 was mailed to Practitioner 3.
- d. On or about April 10, 2014, check number 2391, payable to Practitioner 4, for \$2,000 was mailed to Practitioner 4.

- e. On or about October 17, 2013, check number 13108, payable to Practitioner 5, for \$2,500 was mailed to Practitioner 5.
- f. On or about June 3, 2014, check number 3319, payable to Practitioner 6, for \$1,600 was mailed to Practitioner 6.
- g. On or about June 23, 2014, check number 3457, payable to Practitioner 7, for \$1,000 was mailed to Practitioner 7.
- h. On or about April 28, 2014, check number 2516, payable to Practitioner 8, for \$4,800 was mailed to Practitioner 8.

All in violation of Title 18, United States Code, Section 371.

COUNT TWO
Mail Fraud; Aiding and Abetting
(18 U.S.C. §§ 1341 and 2)

The United States Attorney further alleges that:

21. The United States re-alleges and incorporates by reference paragraphs 1-14 and 16 through 19 of Count One of this Information.

Scheme to Defraud

22. The Defendant and his co-conspirators devised and intended to devise a scheme and artifice to defraud, and for obtaining money and property by means of materially false and fraudulent pretenses, representations, and promises, and used bribes, kickbacks, false statements, material misrepresentations, and material omissions to fraudulently cause insurers to pay for new prescriptions, as well as for increases in dosages and units of new and existing prescriptions.

23. Had the insurers known that the defendants gave bribes and kickbacks to the targeted practitioners, the insurers would not have authorized payment for Subsys because insurers do not authorize payment for prescriptions that are written: (a) in exchange for a bribe or kickback; (b) outside the usual course of professional practice; or (c) not for a legitimate medical purpose

24. The defendants sought to arrange, coordinate, and pay bribes and kickbacks to targeted practitioners throughout the United States, including in the District of Massachusetts.

25. The defendants caused bribes and kickbacks to be sent and delivered by the United States Postal Service and by private and commercial interstate carriers.

26. On or about May 21, 2014, in the District of Massachusetts, and elsewhere, the defendant,

MICHAEL L. BABICH,

having devised and intending to devise a scheme and artifice to defraud, and for obtaining money and property by means of materially false and fraudulent pretenses, representations, and promises, did, for the purpose of executing and attempting to execute the scheme, place in any post office and authorized depository for mail matter, any matter and thing whatever to be sent and delivered by the Postal Service, and take and receive therefrom, any such matter and thing and did knowingly cause to be delivered by mail and by any private and commercial interstate carrier according to the direction thereon check number 3102, payable to Practitioner 2, for \$1,600.

All in violation of Title 18, United States Code, Sections 1341 and 2.

FORFEITURE ALLEGATION
(18 U.S.C. § 981(a)(1)(C) and 28 U.S.C. § 2461(c))

The United States Attorney further alleges:

27. Upon conviction of one or more of the offenses set forth in Counts One and Two of this Information, the defendant,

MICHAEL L. BABICH,

shall forfeit to the United States, pursuant to Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c), any property, real or personal, which constitutes or is derived from proceeds traceable to the offenses. The property to be forfeited includes, without limitation,

a. \$3,500,000 in United States currency, seized on or about October 2, 2017.

28. If any of the property described in Paragraph 1, above, as being forfeitable pursuant to Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c), as a result of any act or omission of the defendant –

- a. cannot be located upon the exercise of due diligence;
- b. has been transferred or sold to, or deposited with, a third party;
- c. has been placed beyond the jurisdiction of the Court;
- d. has been substantially diminished in value; or
- e. has been commingled with other property which cannot be divided without difficulty;

it is the intention of the United States, pursuant to Title 28, United States Code, Section 2461(c), incorporating Title 21, United States Code, Section 853(p), to seek forfeiture of any other property of the defendant up to the value of the property described in Paragraph 1 above.

All pursuant to Title 18, United States Code, Section 981(a)(1)(C), and Title 28, United States Code, Section 2461(c).

Dated: December 26, 2018

ANDREW E. LELLING
United States Attorney

By: *s/Fred M. Wyshak, Jr.*
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